



PATENT
Customer No. 22,852
Attorney Docket No. 08790.0012-00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

John P. DONOGHUE et al.

Application No.: 10/798,919

Filed: March 12, 2004

For: NEUROLOGICAL EVENT
MONITORING AND THERAPY
SYSTEMS AND RELATED METHODS

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) Group Art Unit: 3762

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) Examiner: Kahelin, Michael W.

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) Confirmation No.: 7030

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

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By: 

Brad C. Rametta
Reg. No. 54,387

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1. Reply Brief Under 37 C.F.R. § 41.41 (7 pages)
2. Filing Postcard (1 page)

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

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Attention: Mail Stop Appeal Brief-Patents
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Sir:

REPLY BRIEF UNDER 37 C.F.R. § 41.41

Pursuant to 37 C.F.R. § 41.41, Appellants present this Reply Brief in response to the Examiner's Answer ("Answer") mailed on July 26, 2007. This brief is timely because it is filed within two months from the date of the Answer.

I. Status of the Claims

Claims 1-54, 58-61, 63-115, and 119-151 are pending in this application, with claims 1, 64, 127, 138, 146, and 150 being independent. Of those pending claims, claims 16-19, 23-25, 40-47, 51-53, 78-81, 85-87, 100-104, 112-114, and 127-151 have been withdrawn from consideration.

In the Answer, the Examiner maintains all the rejections raised in the Office Action dated May 18, 2006. For reasons of record and for the additional reasons set forth below, Appellants maintain their position that each rejection is improper and should be withdrawn.

II. Response to Examiner's Arguments in the Answer

A. The Section 102(b) Rejection of Claims 1 and 64 Based on Pless Should be Reversed

1. Pless/Fischell Discloses Comparing Signals With a Threshold Described Only as Preset to Minimize Missing Real Events

In the Answer, the Examiner asserts that the preset threshold of Fischell is based on a previously detected signal "because the rate of false positives disclosed at column 20, line 27, is not an arbitrary value, but set to a specific value of $\frac{1}{2}$ to 5 times as many false positives to 'real' events." (Answer at page 11). The Examiner concludes that "[t]o arrive at this set rate of false positives for a given patient, the threshold that provides this set value must first be determined, or 'previously detected'." (Id. at 11). Appellants disagree.

As previously explained in the record, Fischell merely states that “the thresholds to be used for detection...will typically be programmed to minimize the chance of missing a ‘real’ neurological event even though this could result in the occasional false positive identification of an event.” (Fischell at column 20, lines 19-26). Nowhere does Fischell disclose or suggest that the threshold is a previously detected signal indicative of activity that precedes a neurological event.

The Examiner relies on the Fischell disclosure that the threshold may be programmed to a value that produces from $\frac{1}{2}$ to 5 times as many false positives as “real” events. (Fischell at column 20, lines 26-28). This, however, does not mean that the threshold includes a “previously detected signal.” The threshold value that produces the desired rate of false positives may be set to any value that produces that ratio, including a constant value that is not a previously detected signal. As another example, an initial threshold arbitrarily can be set to ensure a conservative, high rate of false positives. If that initial threshold results in too many false positives, the threshold can be raised to result in fewer false positives. This process can be repeated until the desired rate of false positives is reached. The threshold at no time, however, includes “one or more previously detected signals,” as claimed. Thus, the threshold in Fischell does not necessarily include a previously detected signal. And, even if the preset threshold of Fischell is “based” on previously detected signals, as alleged by the Examiner, which Appellants do not necessarily concede, such a threshold does not necessarily “include” a previously detected signal, as claimed.

Moreover, even assuming, for argument’s sake, that the threshold necessarily includes a previously detected signal, Fischell provides no disclosure or suggestion that

the signal necessarily is indicative of activity that *precedes* the neurological event, as also claimed. The Examiner has yet to provide any such evidence.

The Examiner also asserts that "Fischell further discloses at column 24, line 6, that a time delay 'target signal' is stored, is indicative of activity that precedes a neurological event, and is previously detected (during diagnostic testing)." (Answer at page 11). This interpretation of Fischell is not correct.

As explained in the record, because each electrode 15A-15N may be located at a different distance from the epileptic focus, the processor synchronizes the EEG signals using the appropriate time delay to account for the time it takes the signal to travel from the epileptic focus to each electrode. (Fischell at column 15, line 45 to column 16, line 4). Thus, the time delays of Fischell are established to correct for the different propagation times required for a signal to travel from the epileptic focus to each electrode. Fischell nowhere discloses or suggests that these time delays are previously detected signals indicative of the activity that precedes a neurological event. In fact, Fischell is completely silent with respect to neurological events as they relate to time delays.

Furthermore, the reference to Fischell cited by the Examiner states:

Setting the values for these time delays could be based on measured delays of EEG signals received from an epileptic focus during diagnostic testing of the patient using the implanted system 10 of FIG. 2.

(Fischell at column 24, lines 6-9). This reference does not support the position that time-delayed EEG signals are indicative of activity that precedes a neurological event. EEG signals can refer to any electrical activity associated

with the brain, not *necessarily* those indicative of activity that precedes a neurological event. Consequently, measured delay parameters associated with such random EEG signals are not the same as “previously detected signals indicative of activity that precedes a neurological event,” as claimed.

2. Pless/Fischell Does Not Expressly or Inherently Disclose a Target Signal That Includes a “Previously Detected Signal”

In the Answer, the Examiner maintains the position that the threshold of Fischell inherently includes a “previously detected signal.” In refuting Appellants’ example that a threshold could be selected as an arbitrarily low value to ensure sufficient false positives, the Examiner argues that “an arbitrary threshold cannot be used because the rate of false positives is disclosed as being a set value. Providing a non-arbitrary rate of false positives requires a non-arbitrary threshold.” (Answer at 12.) Appellants have addressed this above. As explained, a threshold value in Fischell that produces a desired rate of false positives does not *necessarily* “includ[e] one or more previously detected signals indicative of the activity that precedes the neurological event,” as claimed.

In refuting Appellants’ example that the threshold may be selected based on data collected from seizure-free test subjects, the Examiner asserts that “pre-selecting a threshold based on seizure-free human or non-human primate test subjects would not violate the limitation that the signal be ‘previously detected signals indicative of activity that precedes a neurological event.’” The Examiner misunderstands the crux of Appellants’ example.

By its example, Appellants further illustrate how the threshold of Fischell could be selected without it *necessarily* including a previously detected signal, as claimed. In this example, a constant-value threshold could be established based on EEG signals collected from “normal” (i.e., neurological event-free) test subjects. This constant-value threshold may, for example, be set to the average amplitude of EEG signals collected from these subjects. This value may be used as a comparative benchmark to identify abnormal neurological activity. Although the threshold may be based on previously detected signals, the threshold is simply a constant value that is not a previously detected signal. As long as this threshold produces ½ to 5 times as many false positives as “real” events, the threshold would conform to the requirements of Fischell, without conforming to the recitations of Appellants’ independent claims 1 and 64.

Accordingly, the threshold of Fischell does not *necessarily* include (as required for inherency) one or more previously detected signals indicative of activity that precedes a neurological event, as claimed.

B. The Section 103(a) Rejection of Claims 1 and 64 Based on Pless and Abraham-Fuchs Should be Reversed

In response to Appellants’ arguments against the Section 103(a) rejection, the Examiner maintains that Pless teaches predicting a neurological event by comparing a signal indicative of the activity that precedes a neurological event. For the reasons noted above and already in the record, Pless/Fischell fails to disclose “a target signal that includes one or more previously detected signal indicative of activity that precedes a neurological event.” The Examiner admits that Abraham-Fuchs is relied on only for its

purported teaching of using previously detected patient-specific data for comparisons.

Abraham-Fuchs, therefore, fails to remedy the deficiencies of Pless/Fischell.

III. Conclusion


For these reasons and the reasons given in Appellants' Appeal Brief filed on February 12, 2007, Appellants respectfully request the Board to reverse the final rejection of claims 1-15, 20-22, 26-39, 48-50, 54, 58-61, 63-77, 82-84, 88-99, 105-111, 115, and 119-126.

To the extent that any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this Reply Brief, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: September 26, 2007

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